

# **EXHIBIT 6**

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF SUFFOLK: PART 48

IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

August 18, 2020  
Central Islip, New York

MINUTES OF FRYE HEARING  
(Testimony of James Rafalski)

B E F O R E: HON. JERRY GARGUILO  
Supreme Court Justice

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1  
2 Q. And, sir, can I ask you to focus on my  
3 questions. There's a regulation that contains that  
4 requirement to report orders of unusual size,  
5 pattern or frequency, correct?

6 A That is correct.

7 Q. You agree with me that that regulation  
8 gives some guidance on a suspicious order, but you  
9 think the actual full definition is up to the  
10 registrar depending on a lot of factors, the scope  
11 of their business, and the scope of those customers  
12 that receive products from them?

13 A Yes, sir.

14 Q. For example, the regulation does not  
15 tell distributors how to figure out if an order is  
16 of unusual size, correct?

17 A That's correct.

18 Q. That's up to the registrar to define,  
19 correct?

20 A Yes.

21 Q. There's no single generally accepted way  
22 to say this is an order of unusual size, correct?

23 A There's not any language specific to  
24 that statement, you mean, no, sir.

25 Q. There's no single generally accepted way

1  
2 to say this is an order of unusual frequency or  
3 unusual pattern, correct?

4 A That is correct, sir.

5 Q. And you're aware that government  
6 watchdogs, some of the ones we talked about  
7 yesterday, have recommended that it would be good  
8 for the DEA to develop additional guidance for  
9 distributors and manufacturers when it comes to  
10 suspicious order monitoring and suspicious order  
11 reporting?

12 A I am aware of that either publications  
13 or that information, yes, sir.

14 Q. And you agree with that recommendation,  
15 correct?

16 A Generally speaking, yes. Maybe not --  
17 maybe you might interpret that question different  
18 than me, but, yes, generally, yes.

19 Q. Using your words in terms of lack of  
20 greater clarity from the DEA, the reason for the  
21 lack of greater clarity from the DEA is that you  
22 don't really think there's a one-size-fits-all  
23 suspicious monitoring system or program, correct?

24 A Yes. I don't think I used that exact  
25 terminology, but that concept would be consistent

1  
2 for the way that I answered about that, yes, sir.

3 Q. There's no one-size-fits-all suspicious  
4 order monitoring system, correct?

5 A Yes, that's correct. Yes, sir.

6 Q. Even today distributors or manufacturers  
7 are left to design their own suspicious order  
8 monitoring programs, correct?

9 A They are, yes, sir.

10 Q. And there's no generally accepted system  
11 saying this is exactly what a suspicious order  
12 monitoring system has to look like, correct?

13 A That's correct.

14 Q. As a result every distributor and every  
15 manufacturers' suspicious order monitoring programs  
16 are different from each other, right?

17 A Yes. Yes. In some ways there are some  
18 differences.

19 Q. And you read, as part of your  
20 preparation in this case, testimony from the DEA's  
21 former head of Office of Diversion Control, Joe  
22 Rannazzisi, correct?

23 A I have read some of his deposition  
24 testimony, yes, sir.

25 Q. I take it you saw that when he was asked

1  
2 about giving guidance or giving a checklist to  
3 registrants as to what's required to be in a  
4 suspicious order monitoring system, he said that's a  
5 business decision based on what the registrant's  
6 needs are, and the Drug Enforcement Administration  
7 does not tell a registrant what that specific system  
8 should look like.

9 Do you remember seeing that testimony  
10 from him?

11 A I do not recall that. I could review  
12 it, if you'd like, but I don't disagree with that  
13 statement.

14 Q. Well, that's where I was going. Maybe I  
15 can short circuit it. Do you agree with the idea  
16 that when it comes to designing a suspicious order  
17 monitoring system, that's a business decision based  
18 on what the registrant's needs are, and the Drug  
19 Enforcement Administration does not tell a  
20 registrant what that specific system should look  
21 like?

22 A I agree with that statement.

23 Q. And I lost you for a second. Did you  
24 say you agree with that statement?

25 A I did. I agree with that statement,

1  
2 sir.

3 Q. Evaluating suspicious order monitoring  
4 programs has to involve a company-by-company  
5 assessment, correct?

6 A You mean a customer-by-customer  
7 assessment?

8 Q. And companies by companies in terms of  
9 their business and who they're dealing with.

10 A Yes. Yes, sir.

11 Q. What works for one distributor or  
12 manufacturer in your view may not necessarily work  
13 for another, correct?

14 A It may work, but I don't think that I  
15 would impose one system from one company on another,  
16 but, certainly there are some businesses that are  
17 very similar that potentially they could work.

18 Q. In your report you lay out some I think  
19 you call it key components that you believe should  
20 be included in a suspicious order monitoring system.  
21 Are you aware of that?

22 A In my report?

23 Q. Yes, sir.

24 A I don't know if I say they should be  
25 included, if that's my exact language. I think that

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I might say that one would expect to see, but yes, sir.

Q. Well, actually that's where I'm going, is it possible to have a compliant suspicious order monitoring system without all of those components?

A Depending on the scope of business or the type of customer, I think it's possible to not include some of those things.

Q. Okay. There are no -- stated differently -- there are no generally accepted set of requirements that every single suspicious order monitoring program must have, correct?

A Correct statement.

Q. Let's look at Plaintiff's Exhibit 1. Chris, it's Tab 1 in the binder that we -- it's Tab 1 in our document set that we used yesterday.

This is your report, Mr. Rafalski, and could we put that up on the screen, please? Page 45, please. You have a section of your report that says, Analysis of the methodologies to quantify suspicious orders distributed in New York. Do you see that?

A Yes, sir.

Q. And if you look down near the bottom



review.

Q. Okay. I want to go back to your methods. You talked a lot yesterday about what you did while you were at the DEA. Am I correct that while you were at the DEA, the DEA never analyzed ARCOS data using the methodologies that Dr. McCann presented and you also presented in your report?

A That exact specific scenario, no, sir.

Q. You never used those methodologies, correct?

A No, sir.

Q. And I think the way I'm asking the question, I just want to make sure we're not talking past each other. What I said is correct, yes?

A I never specifically applied these methodologies during one of my occasions, and I'm not aware that the DEA did. I'm not saying they didn't, but typically these methodologies, no, sir.

Q. Thank you. Before I dive into Methodology A, which is the one I'm going to focus on because it's the one that you rely on, I want to cover some general points about your work regarding flagged orders and suspicious orders.

And let's go back to Plaintiff's Exhibit

diligence file.

Q. That's true for all distributors?

A Yes, sir.

Q. That's true for all manufacturers?

A Yes, sir.

Q. That's true for pharmacy Defendants in this case?

A Every specific due diligence file, that's a correct statement, yes, sir.

Q. You told us yesterday that it is absolutely important that there be an uninterrupted supply of prescription opioids for patients who need them. Do you recall that testimony?

A I stand by that statement.

Q. You agree that manufacturers and distributors and pharmacies play an important role in ensuring an adequate and uninterrupted supply of legitimate prescription opioids, correct?

A Yes, sir.

Q. And relevant to ensuring the distributors and pharmacies and manufacturers play that role, that critical role in ensuring an adequate and uninterrupted supply of legitimate prescription opioids, you don't have an estimate as

1  
2 to how much of prescribing or prescriptions are  
3 legitimate in terms of prescription opioids?

4 A I wasn't requested to conduct that  
5 analysis so, no, sir, I do not.

6 THE COURT: Mr. Schmidt, in connection  
7 with strictly a Frye analysis, strictly a  
8 Frye analysis, where are you going with this  
9 line of questioning?

10 Frye analysis over here, and, of course,  
11 examination during the trial of foundational  
12 material.

13 It seems to the Court, and perhaps it's  
14 far from me to question your needs and  
15 methods -- pardon the play on the words  
16 gentlemen and ladies -- what's the  
17 connection?

18 The Frye analysis -- the Court expects  
19 to hear a detailed explanation of  
20 methodology. The Court expects to hear  
21 testimony as to general acceptance or  
22 consensus of the methodology and testimony as  
23 to reliability.

24 It seems to the Court that a great deal  
25 of your examination is dealing with the

1  
2 Now, was it -- did they use specifically  
3 a, you know, methodology or diagnostic tool A, B, C,  
4 or D, no, but within the DEA, I believe the same  
5 type of analysis was conducted to come to some  
6 conclusion on some of the cases, yes, sir.

7 Q. Okay. That's not my question, sir.  
8 Please focus on my question. Can you point me to  
9 any time you're aware of when anyone has used Method  
10 A to try to estimate, not flagged orders, not even  
11 suspicious orders, but actually diverted orders?  
12 Yes or no.

13 A No.

14 Q. Is it generally accepted? Is there any  
15 measure of general acceptance you can point me to  
16 for using Method A to estimate, not flagged orders,  
17 not suspicious orders, but actually diverted orders,  
18 as you have done in your testimony?

19 A No.

20 Q. Are you aware that the DEA has actually  
21 used techniques to try to estimate the amount of  
22 diversion?

23 A Yes.

24 Q. And are you aware of the numbers that  
25 they have come up with when they use those

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A Yes, sir.

Q. We can take that title down. If you look across the top, there's a year of -- there's a range of years. I'm going to focus on what DEA was focused on, 2018. Do you see that?

A Yes.

MR. SCHMIDT: And I'm sorry that this is not the most elegant way to be able to show this to you. It's hard doing this remotely, but, Chris, could we call out the line for hydrocodone sale and oxycodone sale, please.

BY MR. SCHMIDT:

Q. And I hope you can see this with me, Mr. Rafalski. I just want to lay out what the math is, and then I'll tell you what I get from these numbers.

The hydrocodone estimated diversion from the DEA is, if we look at the left, 24.259. Do you remember that number?

A Yes.

Q. And if we divide that by the 2018 number for total hydrocodone it's 43,027.640, correct?

A Yes, sir.

Q. And that comes up to .056 percent. Does

1 that sound right to you?

2 A Yeah. I wouldn't argue with that. I'm  
3 not going to calculate it, but...

4 Q. And let's just do the same for  
5 oxycodone. It's kind of covered, if you can pull  
6 the left side down a little bit, Chris. There we  
7 go.  
8

9 So for oxycodone the amount of diversion  
10 for 2008 is 57.051; do you see that?

11 A Yes, sir.

12 Q. Divided by 79,596.606. Do you see that?

13 A I don't see the .606. Is that the  
14 calculation you're doing?

15 Q. No. That's the number at the end of --

16 THE COURT: It's a suggested  
17 calculation.

18 MR. SCHMIDT: No, it's actually not.  
19 That's the number reported in Exhibit I of  
20 the table. It's probably hard to read.  
21 Maybe we can blow up that number a little  
22 bit, the 79,596.606 under 2018, Chris.

23 BY MR. SCHMIDT:

24 Q. Do you see that?

25 A I can see that number, but my

1 Q. Okay. And you don't have alternative  
2 numbers using either their methodology or any other  
3 methodology for actual diversion for years other  
4 than 2018, correct?

5 A I do not.

6 Q. Okay. Let me go back to some of the  
7 questions I was asking you. Do you know if any of  
8 the orders that were flagged by Dr. McCann's  
9 methodology that you adopted, do you know if any of  
10 those orders were actually diverted?

11 A When you say the word "actually," I have  
12 to answer that no, sir.

13 Q. You don't know?

14 A No, sir.

15 Q. To the contrary, would you agree with me  
16 that just a suspicious order in an amount outside of  
17 the normal, which is either an amount that's a large  
18 order, orders that are frequent orders, or the other  
19 criteria that's listed in the regulation, that in  
20 itself doesn't mean guarantee that it's going to be  
21 put into an illicit market?

22 Do you agree with that? And I'll just  
23 ask, I don't know if you heard the end of what I  
24 said. Someone was not on mute, so I'll just ask  
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you turned in this report, did you?

A Well, your first question was pretty broad. Specifically about this report, no, sir.

Q. You didn't read his deposition in the New York case, did you?

A I read portions of it.

Q. But not in its entirety?

A No, not the entirety.

Q. You've not checked his calculations, have you?

A Definitely I have not done that, sir.

Q. And in terms of what we see on this page, your Method A, this is, again, copied in this case word for word and number for number from what Dr. McCann did, correct?

A That would be my expectations, yes, sir.

Q. You didn't change anything?

A I did not.

Q. And even the format that this appears in, that was given to you and adopted by you as your own, in your words, correct?

A The Excel spreadsheet system, yes, I didn't design this. That's correct.

Q. You didn't know, until we talked at your



1  
2 deposition, that in coming up with these numbers and  
3 getting from the data to the opinions you offered,  
4 the methodology he used that you adopted, you didn't  
5 know until we talked at your deposition that he had  
6 to make some judgment calls in coming up with these  
7 numbers, did you?

8 A So I remember that testimony, and I  
9 think there were some -- I think the term that was  
10 used was assumptions, and I was a little confused by  
11 that.

12 I know there was some questions on how  
13 to apply the methodology, and I -- so I may have  
14 answered that I did not know, but I think I was  
15 confused by the question.

16 Q. You knew his algorithm required certain  
17 judgment calls?

18 A Well, I had some discussions or -- not  
19 directly with him in regards to the start and stop  
20 point, whether it was 30 days or whether it was  
21 calendar months, but specifically I know there was a  
22 little bit of he needed to make some assumptions or  
23 judgments to run it, but specifically, I didn't have  
24 any conversations directly with him about it.

25 Q. And you can't say, one way or another,

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2       whether you agree with the judgment calls he made in  
3       performing his algorithm, correct?

4           A       That's not a totally true statement.  So  
5       on applying the Methodology A, if you went by the  
6       calendar months, I would agree.  I agree with that.

7 Q. Is it true that you don't know the  
8 entirety of his judgment calls?

9                   A       I reviewed his deposition testimony.  If  
10       there's some outside of that, I would not be aware  
11       of them.

12 Q. Okay. Let's look at your February 7th,  
13 2020 deposition transcript, page 204, line 13 to 22.  
14 This is Tab 2, page 204, 13 to 22.

15                   "QUESTION: Okay. Maybe that answers my  
16                   next question, which is do you know, can you  
17                   say one way or the other whether you agree  
18                   with the judgment calls he made in performing  
19                   his algorithm?

20                   ANSWER:  I don't know the entirety of  
21                   his judgment call, so I can't, I can't answer  
22                   that question."

23	Did I read that correctly?
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24                                   A        You did.

25 Q. Do you recall being asked that question

1  
2 and giving that answer at your deposition?

3 A I don't specifically recall it, but I  
4 don't dispute the deposition record.

5 Q. Do you dispute the truth of that  
6 statement?

7 A Yes, sir.

8 Q. You do dispute the truth of that  
9 statement that you made?

10 A I do not. I'm sorry.

11 Q. Okay. And you looked at his testimony.  
12 Do you see the part of his testimony where he said,  
13 I probably would come up with 5 or 10 different  
14 small decisions that needed to be made in order to  
15 operationalize it? Did you see that portion of his  
16 testimony?

17 A I don't specifically recall that.

18 Q. Okay. Do you know what the 5 to 10  
19 decisions he had to make to be able to perform his  
20 Method A calculation that you relied on? Do you  
21 know what those 5 to 10 decisions were?

22 A No, sir.

23 Q. So not knowing how he took the data and  
24 made the 5 to 10 decisions, you don't know how far  
25 of a gap there is between his outputs and that

1 additional data in terms of those 5 to 10 decisions  
2 that he made. Am I correct in that?

3  
4 A Yes, sir. That's correct. That is a  
5 correct statement.

6 Q. Now, let's show the Judge how your  
7 method works in application. Under your Method A,  
8 you look to see if the level of opioids in a given  
9 month is more than any in the prior single six  
10 months, right?

11 A Trailing six months, yes, sir.

12 MR. SCHMIDT: And if we illustrate that,  
13 can we pull out Demonstrative Exhibit 4?  
14 We'll mark this as Court Exhibit K. Let me  
15 just give a moment for it to be passed out in  
16 court.

17 BY MR. SCHMIDT:

18 Q. So do you see I've written up on the  
19 screen, Year 1. I start in February, 5,000, go  
20 through July, and the number of pills vary per  
21 month, 5,000, 10,000, 7,000, 8,000, 9,500. Do you  
22 see that?

23 A I do.

24 Q. And do you recognize that these are the  
25 very same numbers that Dr. McCann gives as an